REMARKS

Applicants respectfully request entry of the amendments and remarks submitted herein. Claims 1-13 have been canceled herein without prejudice to continued prosecution, and new claims 14-36 have been added herein. Support for new claims 14-36 can be found, for example, in the originally filed claims and throughout the specification.

Claims 14-36 are currently pending. Reconsideration of the pending application is respectfully requested.

The 35 U.S.C. §112 Rejection

Claims 4-6 and 8-12 stand rejected under 35 U.S.C. §112, second paragraph, because, according to the Examiner, a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation in the same claim is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired (OA at page 2).

Applicants have rewritten original claims 1-13 as new claims 14-36. New claims 14-36 do not contain the "preferably" language, and new claims 14-36 also do not contain a broad range or limitation together with a narrow range or limitation. Therefore, Applicants respectfully submit that the rejection of the original claims under 35 U.S.C. §112, second paragraph, is moot, and should not be applied to any of the new claims.

Claims 7-10 stand rejected under 35 U.S.C. §112, second paragraph, as the Examiner asserted that those claims are indefinite for failing to particularly point out and distinctly claim the subject matter that Applicants regard as the invention. According to the Examiner, a claim is rendered indefinite when the claim merely recites a use without any active, positive steps delimiting how this use is actually practiced (OA at page 4).

As indicated herein, original claims 1-13 have been canceled herein and new claims 14-36 submitted. New claims 14-36 do not include any "use" claims. Therefore, Applicants

respectfully submit that the rejection of claims 7-10 under 35 U.S.C. §112, second paragraph, is moot, and should not be applied to any of the new claims.

The 35 U.S.C. §101 Rejection

Claims 7-10 stand rejected under 35 U.S.C. §101 as being drawn to use claims, which, the Examiner indicated, are non-statutory process claims (OA at page 4).

As indicated above, original claims 1-13 have been canceled herein and replaced with new claims 14-36. New claims 14-36 do not include any "use" claims. Therefore, Applicants respectfully submit that the rejection of claims 7-10 under 35 U.S.C. §101 is moot, and should not be applied to any of the new claims.

The 35 U.S.C. §102 Rejection

Claims 1, 2 and 11-13 stand rejected under 35 U.S.C. §102(b) as being anticipated by Oobae et al. (US 2002/0042393). According to the Examiner, the claim limitation that the specific surface area [of the trehalose particles] is greater than 0.25 m^2/g is inherent in the particles of Oobae et al. since Oobae et al. teaches the claimed size of trehalose particles and also teaches particles having the same density, which corresponds to the mass/unit volume (OA at page 5). This rejection is respectfully traversed.

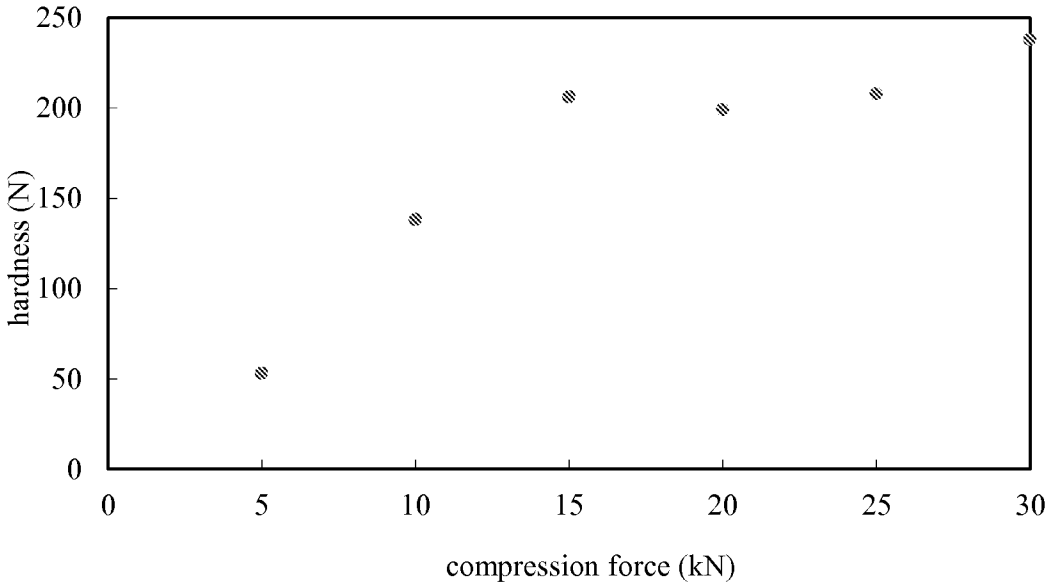
Oobae describes an excipient comprising trehalose having a purity of 99% or more, where 2 to 90% wt% of the trehalose particles are 75 μm or more in size, where the average size of the trehalose particles is 10 to 250 μm, where the trehalose has an apparent specific volume of 1.5 to 3.5 ml/g, and where the trehalose has a whiteness of 90% or more (see, for example, the Abstract). Oobae et al. discloses that the trehalose can be obtained by subjecting commercial trehalose crystals to an appropriate combination of processing steps selected from purification, grinding, sieving, crystallization, and the like (see, for example, paragraph [0043]). Oobae et al. discloses that an appropriate combination of processing steps is one that removes glucose (see, for example, paragraph [0043]).

In addition, Table 1 (on page 12 of Oobae et al.) describes certain properties of the trehalose prepared by Oobae et al. It would be understood by those skilled in the art that the

melting point of 97°C shown in Table 1 clearly indicates that that product is a trehalose dihydrate, while the melting point of 203°C shown in Table 8 (on page 13) indicates that the product is a trehalose anhydrous. Oobae et al. discloses that the anhydrous crystals absorb moisture during storage (column 9, paragraph [0128]), resulting in a significant decrease in the hardness of the tablet. Compare, for example, Table 2 (on page 12) with Table 9 (on page 13).

The pending claims are directed to trehalose solids having a high specific surface area but yet having a low hygroscopicity (see, for example, paragraph [0030] in the present application). The claimed trehalose solids, because they contain a mixture of trehalose dihydrate and anhydrous trehalose, benefit from a synergistic effect resulting in superior properties such as direct compressibility, lower hygroscopocity than anhydrous trehalose, and improved flowability compared to amorphous trehalose (see, for example, paragraph [0032]). Figure 1 in the present application shows that the material is completely crystalline and that both dihydrate and anhydrous crystals are present (see, for example, paragraph [0022] and [0062]). Figure 1 also shows that the claimed trehalose solids do not have just one melting peak, which is significantly different from the trehalose crystals of Oobae et al., which has a purity of 99% or more (see, for example, the Abstract).

The claimed trehalose solids impart very different properties than simply using trehalose, which can be seen from the hardness of tablets containing the claimed trehalose solids. Figure 2 in the present application shows the tensile strength of tablets prepared with the claimed trehalose solids. The tensile strength is expressed as a function of increasing compression force. Paragraphs [0072] and [0073] in the present application indicate that the hardness was recalculated as tensile strength (N/mm^2) taking the dimensions of the tablets into account. For the convenience of the Examiner, a figure is provided below that corresponds to Figure 2 in the present application, but, in the figure below, the hardness is expressed in N (i.e., hardness was not recalculated in tensile strength). From this figure, one can see that tablets containing the claimed trehalose solids have a hardness of at least 50 N.



On the other hand, Oobae et al. discloses the hardness of their tablets obtained with their trehalose was 2.3 - 2.6 kgf (see, for example, Table 2 on page 12). Those skilled in the art would appreciate that 1 kgf corresponds to 9.807 N; as such, the tablets prepared using the trehalose of Oobae et al. have a hardness of between 22.6 N and 25.4 N. Therefore, the currently claimed trehalose solids provide tablets that are much harder than those of Oobae et al.

Based on the comments above, the claimed trehalose solids and tablets made with such trehalose solids are significantly different than the trehalose of Oobae et al. or products made with the trehalose of Oobae et al. Accordingly, Applicants respectfully submit that the rejection of original claims 1, 2 and 11-13 under 35 U.S.C. §102(b) is moot, and, based on the remarks set forth herein, should not be applied to the corresponding new claims.

The 35 U.S.C. §103 Rejection

Claims 3-6 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Oobae et al. in view of Kinouchi (US Patent No. 5,441,644) and JP 2001-213890. According to the Examiner, it would have been obvious to one of ordinary skill in the art at the time the claimed

invention was made to make crystalline trehalose by heating an aqueous solution of trehalose above its temperature of solubility, applying shear and cooling to obtain trehalose solids, as suggested by Kinouchi, to product the present invention. The Examiner asserted that one of ordinary skill in the art would have been motivated to do so because Oobae et al. teach using trehalose of 99% purity or higher and Kinouchi teaches a method of obtaining trehalose of 99% purity or higher (OA at page 10). Applicants respectfully traverse this rejection.

As indicated herein, original claims 1-13 have been canceled and new claims 14-36 have been introduced herein. The new claims require that the trehalose comprise mixtures of trehalose dehydrate and anhydrous trehalose and be sheared to a particular extent (as measured by specific surface area). As disclosed in the present application, this particular combination results in a form of synergy (see, for example, paragraph [0032]). On the other hand, neither Oobae et al. nor Kinouchi discloses the claimed method of making trehalose solids, which includes the combination of trehalose dehydrate and anhydrous trehalose sheared to a particular extent, and which results in a unique product having the claimed properties.

Furthermore, the table below demonstrates that the crystalline form that is prepared using the claimed methods is different from the crystals prepared by Oobae et al. The table below describes the properties of commercial trehalose dihydrate ("Trehalose") and the properties of the claimed microcrystalline trehalose solids ("Microcrystalline Trehalose").

		Trehalose	Microcrystalline Trehalose
Density	g/cm3	0.68	0.52
Moisture content	%	9.10	9.02
Specific surface	m2/g	0.04	0.02
Flodex flowability		4	>34
Particle size	μm	470	87

The table above is simply provided for illustrative purposes, and demonstrates that, while certain properties of trehalose and the claimed microcrystalline trehalose solids might be the same, it does not necessarily mean that all of the other properties are the same. The current properties, such as the combination of trehalose crystals sheared to the recited specific surface

area, have been particularly selected to obtain a new and non-obvious composition of trehalose solids.

There is nothing in any of the cited references that would suggest the particularly claimed methods to arrive at the particularly claimed properties. Accordingly, Applicants respectfully submit that the rejection of claims 3-6 under 35 U.S.C. §103(a) is moot and should not be applied to the new method claims.

CONCLUSION

Applicants respectfully request allowance of claims 14-36. If a telephone call to the undersigned would help to expedite prosecution, the Examiner is encouraged to do so. Please apply the fee for the enclosed Petition for Extension of Time and any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

/June 9, 2011/

Date:_____

/M. Angela Parsons/

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